510(K) SUMMARY

Premarket Notification for VISTEO Device

K093105

Submitter
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OCT 1 8 2010

Application correspondent **Jay Mansour**
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Device name
Proprietary name: VISTEO
Classification name : Extra oral source X-Ray System accessory
Common name : Digital dental imaging device

Predicate devices
UNIVERSAL-X : **K053172** Manufacturer/Applicant = **OWANDY**

Device description
The VISTEO system consists of the following components: the sensor and its cable, a USB/data box, with sensor adapter. The sensor body is made hermitically sealed shell which encapsulates a black and white CMOS chip.
The sensor attaches the USB/data box (processing unit) via a 1 meter removable cable.
The sensor, when exposed to radiation, captures image in the form of a charge pattern on its surface (CMOS). The resulting electronic signals are digitised and sent to a computer for image presentation.
According to the 2 different models, there are two possible sizes:
D001 model (size 1): the outer dimensions are approximately 1.5 x 1.0 x 0.3 inches (38,9 x 24,9 x 7,4mm) with rounded edges.
D002 model (size 2): the outer dimensions are approximately 1.7 x 1.2 x 0.3 inches (42,9 x 30,9 x 7,4mm) with rounded edges.

The USB/data box relays the data from to the computer for display. The data box is a 5.4 x 1.8 x 0.7 inches (13.8x 1.8 x 0.7 cm) box with an USB cable connection.

Positioner accessories : 2 bite blocks (bitewing and endo) + 1 aiming ring

Intended use

The VISTEO digital system is used to provide instant digital images of human oral tissue and teeth without the use of a conventional x-ray film. It is used for diagnosis purpose, by dental practitioners.
This is achieved by using the conventional x-ray tube, and placing an electronic sensor in the patient's mouth instead of conventional film.
The sensor, upon radiation exposure, automatically captures the images into a computer.
The computer, which is not provided by OWANDY, controls all aspects of image acquisition and image display, storage and printing.
Additional software (after, and not part of, image capture software) is available on the market. They allow for enhancements such as zoom, contrasts controls, image inversion, and pseudo color renditions.
The main advantages of this digital imaging system are :
- high definition ensuring high-value diagnostics
- interface allowing image processing in the PC
In no case, it has to be used directly by the patient. So, it is used exclusively in a healthcare specific environment.

Substantial equivalence and technological characteristics

The VISTEO device is substantially equivalent to the UNIVERSAL-X predicate device , legally marketed in the United States (K053172) by OWANDY in 2006.
The VISTEO and the predicate devices are intended to be used with Dental X-ray source, Dental Image Management Application Software and standard computer hardware for the capture, evaluation and storage of high quality digital dental X-ray mages using existing X-ray equipments.
The system and its predicates all consists of a X-ray sensitive solid state imaging array (CCD technology for the predicate, CMOS technology for the VISTEO) installed in the Dental X-ray device in place of the traditional photographic film, connected via cable to digitizing and control electronics which, in turn, interface to a computer via a standard interface. The proposed and predicate devices are intended for patients receiving routine dental radiography, in a clinical environment by dental professionals.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
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OWANDY
% Mr. Jay Mansour, MSQA, BE, RAC, LA
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OCT 18 2010

Re: K093105
Trade/Device Name: Visteo
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: EHD
Dated: August 23, 2010
Received: August 26, 2010

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David G. Brown, Ph.D.
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

OCT 1 8 2010

510(k) Number (if known): K093105

Device Name: VISTEO

Indications for Use:

The VISTEO digital system is designed to collect instant images of human oral tissue and teeth without the use of a conventional x-ray film.
It is used with a conventional X-ray tube and a Computer for dental radiographic imaging.
The VISTEO is covered with a single use disposable sheath and positioned in the oral cavity opposite the tooth the dentists wishes to X-Ray.
The dental X-ray tube (which is not part of VISTEO) is pointed at the sensor and activated.
The emitted radiation from the X-ray tube is detected by the sensor and transmitted as a data stream to the computer system that the device is connected to.
In no case, it has to be used directly by the patient. So, it is used exclusively in a healthcare specific environment.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR ~~Over-The-Counter Use~~ ~~(21 CFR 801 Subpart C)~~

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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